Certification and Adoption Workgroup
Draft Transcript
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Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good morning and welcome everybody to the certification and adoption workgroup. This is a federal advisory committee meeting which means that there will be an opportunity at the close of the meeting for the public to make comments. Now, let me do a quick roll call. Paul Egerman?

Paul Egerman – eScription – CEO
Yes, good morning.

Judy Sparrow – Office of the National Coordinator – Executive Director
Marc Probst? Rick Chapman or Larry Wolf from Kindred?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Yes.

Judy Sparrow – Office of the National Coordinator – Executive Director
Adam Clark?

Adam Clark – Lance Armstrong Foundation – Director for Health Policy
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Charles Kennedy? Scott White can't make it. Latanya Sweeney? Steve Downs? Micky Tripathi? Joseph Heyman? Teri Takai? Carl Dvorak? George Hripcsak? Joan Ash?

Joan Ash – Oregon Health & Science University – Professor and Vice Chair
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
William Munier? Paul Tang?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Did I leave anybody off?

William Munier – Center for Quality Improvement and Patient Safety Agency – Director
This is Bill Munier. I just joined.

Judy Sparrow – Office of the National Coordinator – Executive Director
Oh, good. Thank you. Welcome. I'll turn it over now to Paul Egerman.

Paul Egerman – eScription – CEO

Great, thank you very much, Judy, and just say good morning to everybody. Thank you for joining our call. I also want to say good morning and welcome to the public who might be listening in on our call. We appreciate your participation. We have a very interesting agenda we want to do.

I first want to do a quick administrative idem to make sure everybody understands where we are on the NPRM and our comments on the NPRM which we discussed last week. What we're going to be doing in the next day or two we'll be writing up those comments and circulating them to you asking you to review them and tell us whether or not it's correct, or if there are any adjustments we need to make, we'll do that by email.

Then on Monday, April 5 there's a policy committee meeting scheduled. I think it starts at 10:00 in the morning, and basically, the purpose of that meeting is going to be to review the workgroup's comments and hopefully approve them by the policy committee in which case then they'll be submitted. You should expect to see an email on the certification comments in the next day or two. Unfortunately, it's going to have a short timeframe, but probably like two or three days for you to review it and respond to it.

The agenda for today is really we have sort of two topics. One is to have the discussion about FDA. We had gotten through our work document all the way up to the last topic, which is the FDA, so that's the remaining topic. We'd like to have a discussion on that topic, and then what we are going to do is if there's time remaining is circle back on what I would call the second document, revised working document to make sure that that accurately reflects our discussions on the other issues, and then we can review where we are. Those are the two things for today, the FDA and then reviewing the rest of the discussion.

Then on the FDA what I tried to do was to sort of help us structure our discussion. I did my best to write up the various comments I heard from members of the workgroup in emails and discussions that we had as a summary. What I wanted to do was almost like to structure this in three sections. The first section will be to say what are the areas where we have concerns, and are they correctly and accurately described in the concerns. The second area is what are the places where we see opportunities for ONC to collaborate with FDA. The third segment is going to be what recommendations if any do we want to make to the ONC about how they should work with the FDA. That's how we're going to try to structure this.

The first part is the concerns. Let me just say if people have had a chance to read the document, what are your reactions to what is written here?

Joan Ash – Oregon Health & Science University – Professor and Vice Chair
This is Joan, and I thought you did an amazing job capturing what we had discussed about this. I just had one little thing to add to 9D about the incremental nature of HIT development and the fact that we believe that FDA oversight could harm the ability to innovate. In fact, I offered a sentence saying that by hampering and slowing down the ability of vendors to continuously improve systems thus making them safer, such a process could actually work against the safety efforts we're proposing. I do think that, at least according to some of the testimony we heard, there could be a slowing down of the ability of vendors to react to safety issues.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Can I ask a clarifying question?

Paul Egerman – eScription – CEO
Sure.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
This is Paul Tang.

Paul Egerman – eScription – CEO
Thank you, ask everyone to say your name before you talk, so go ahead, Paul.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
The QSR process, I believe that's certifying a process by which you develop and test software applications. So once you have a process to design, develop, test, and QA the software you write, that process is intact. It's not saying that you have to check the process every time you write new code. Am I correct about that or am I incorrect?

Paul Egerman – eScription – CEO
First of all, it's a great question and I want to do my best to answer it. I might be on a little bit of thin ice there, so I hope if I get this wrong somebody will either maybe if they're listening will email me the correct answer or we'll find out, but my understanding is the QSR process is part of that class 2 regulation from FDA and that this is a fairly strict process. It's the things that you have to do, and it's not just one time in terms of how you develop the software. It's how you do everything, how you do any iterative change, how you do any new release. There's a clearly laid out process as to what has to happen. It is a process that the software vendors, the PAC vendors, and the blood bank vendors claim, whether the claim is right I don't know, but they claim that that sort of limits innovation; makes it harder to develop things.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Is there a write up we could look at the QSR process? For example, if it's just a quality process that you follow to develop software, it seems that that by itself isn't a limiting tact. If it's that every time you make a change in the code you have to get it approved, which I think does apply to the 510(k) products, then that certainly slows things down. I just want to make sure we have the difference correct.

Paul Egerman – eScription – CEO
Yes, and that's fine. We actually did get copies from the FDA of the QSR process, and I can send that out to you again. I don't know the answer to your specific question as to whether or not you have to do 510(k) for every change, but I do know you have to go through the process for every change, and so that's where the concern is. That's also only with, if I understand it right, it's only with class 2 regulation. In other words, if you're in class 1, then you don't have to do that, but there are these three classes, and class 2 is where there's significant concern.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Do people agree that having a quality process is okay or is that also an issue?

Paul Egerman – eScription – CEO
Good question. It's unfortunate Carl's not on the phone.

Carl Dvorak – Epic Systems – EVP
No, he's here.

Paul Egerman – eScription – CEO
Terrific.

Carl Dvorak – Epic Systems – EVP

Yes, I just joined three minutes late. Sorry about that.

Paul Egerman – eScription – CEO
Okay, good morning, Carl. Paul Tang's asking questions about the QSR process. Did you hear the question?

Carl Dvorak – Epic Systems – EVP
I think I heard the question. It was just do people, well, maybe re-ask it, Paul? Sorry.

Paul Egerman – eScription – CEO
The question is are we expressing concern about quality development processes in general, or are we expressing concern about the QSR process in particular?

Carl Dvorak – Epic Systems – EVP
Yes, I think the concern is around the FDA requirements around their brand of QRS process. I think having a process is a good thing, and it could be put down as a requirement in a different manner. I think the real concern is the way FDA administers things and sets its requirements it's not really as conducive as it sounds on the surface.

Paul Egerman – eScription – CEO
I understand that. In making that comment, what I was trying to do was make sure that members of the workgroup can make comments on all these issues, but I actually have personal experience with this. In my first company, IDX, having gone through the 510(k) process where I think it was PAC software, and basically, I could tell you what the internal discussion was at the time. We felt that that process, we didn't think it was terrible. It was doable. It had at least a six-figure cost associated with it, and we felt that it had actually benefits for our organization. The benefits were it made it harder for new entrants to come into our field, and it made it more difficult for us to do continuing development so that we didn't need to do new releases every year. We could do new releases much slower as a result. It basically leveled the playing field in that there would be very little new developments in the software areas that we had. While that was an interesting vendor viewpoint, I don't think that's a good consumer viewpoint.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Paul, the whole question, I think, is around whether the 510(k) approval, that's a premarket approval, correct?

Paul Egerman – eScription – CEO
No.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
No? Okay, then I'm—

Paul Egerman – eScription – CEO
There's a whole premarket approval process which is I think the class 3. My understanding is this is part of class 2. This is also the section I think that Alan Morris was complaining about.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
As long as it's only the QRS process that you're saying is holding up innovation in a justified way, then this statement is right on.

Paul Egerman – eScription – CEO

Again, Carl, since you're the one who's got the real-world experience, I tried to reflect your comment in this. Is this accurate the way I wrote it?

Carl Dvorak – Epic Systems – EVP
Yes, I think so. I would agree with it.

Paul Egerman – eScription – CEO
Then Joan is suggesting expanding this by suggesting that to the extent that we hamper innovation, it's actually counterproductive to the goals on patient safety is what I paraphrased what she's saying. She actually wrote it much better than I just said it. I assume that that is okay, too. Unless somebody has some other comments about the QSR process, are there other comments about these FDA concerns that I wrote down in terms of whether or not their correct or accurate or reflect what people think?

Maybe we should sort of walk through them one by one. The first one is the FDA focus on vendors who market their products. This is the comment about open-source software. I was a little uncertain about the self-developed software because indeed Alan Morris was dealing with some self-developed software that seems to be FDA-regulated, so I wasn't sure I understood that part right. I don't know if Marc Probst is on the phone or if people thought I wrote out that first one correctly.

Marc Probst – Intermountain Healthcare – CIO
I'm on it, Paul, and I noticed you modified it a little based on our interaction. I'm just not sure. I know that Alan does have interaction significantly with the FDA relative to a lot of these decision support products he's developing.

Paul Egerman – eScription – CEO
Yes, and I didn't know if that was because they were closed loop software systems or if they were connected to a regulated device because if you connect something a regulated device like a PAC system or something, then you have to do—

Marc Probst – Intermountain Healthcare – CIO
They're an open loop product.

Paul Egerman – eScription – CEO
They are, okay, so maybe we need to make sure we research that issue before we send it out. The issue is to what extent self-developed—

Marc Probst – Intermountain Healthcare – CIO
I can send it to Alan and get his comment.

Paul Egerman – eScription – CEO
But my understanding from the hearing was that open source is not. Is that correct? Did people have the same understanding?

Marc Probst – Intermountain Healthcare – CIO
I didn't get that understanding, but I don't know.

Paul Egerman – eScription – CEO
I know that was the whole interaction that Carl had with Jeff about—

Carl Dvorak – Epic Systems – EVP

Yes, I think his words were they would take a complete hands-off approach to open source and to self-developed, and then he asserted at one point that vendor-provided software is riskier than open source, and then I asked him why the agency thought that. I think he came back up to the microphone during the public comment period and reversed course on that issue.

Paul Egerman – eScription – CEO
Yes, anyway, Carl, this is Paul Egerman. That's the way I recall that discussion, too, although I think he did say that self-developed, if it gets remarketed to another institution, then it would be …

Joseph Heyman – AMA – Board Chairman
Paul?

Paul Egerman – eScription – CEO
Yes.

Joseph Heyman – AMA – Board Chairman
This is Joe Heyman.

Paul Egerman – eScription – CEO
Hi, Joe.

Joseph Heyman – AMA – Board Chairman
I was kind of muted so I couldn't say anything. I had to call in again. Have you guys left the FDA discussion already?

Paul Egerman – eScription – CEO
No, we are just starting the FDA discussion.

Joseph Heyman – AMA – Board Chairman
Okay, I just wanted to make sure. I just had two quick comments on the FDA discussion.

Paul Egerman – eScription – CEO
Please go ahead.

Joseph Heyman – AMA – Board Chairman
All right, one is the, I forget who it was, but somebody said that it leveled the playing field, but I have to say that if there's a six-figure cost making an application, that doesn't level the playing field. It makes the more large, better financed companies have success at the expense of the smaller companies that can't afford that and may have some innovative ideas.

The second thing was that I had made a suggestion in the email for the very final recommendation. I had suggested that we say that ONC work with the FDA and representatives of patients, clinicians, vendors, and healthcare organizations to determine the role the FDA should play to improve the safe use of certified EHR technology rather than the sentence that suggests some broad public input. I say that because broad public input can be very general, but I think that we want to make certain that stakeholders have something to say about this. I think otherwise the document is spectacular.

Paul Egerman – eScription – CEO

We'll do the last one first of what you said, extending broad public comment to make sure that we list the stakeholders of the patients, the clinicians, and the healthcare organizations. I think that's an excellent suggestion. I think we'll just go ahead and do that.

The first thing you said that I also want to make sure we capture is the fact that you're saying perhaps you feel it's not already expressed. You're just saying the cost of FDA regulation could be a barrier to entry for new entrants and could harm small participants. That's a concern you want to list separately. Am I hearing that right?

Joseph Heyman – AMA – Board Chairman
Well, I wasn't sure that it needed to be listed. I just wanted to make the point because I think from a large vendor point of view something that's leveling the playing field may actually be something completely annihilating a smaller company.

Paul Egerman – eScription – CEO
Yes, and I think that's a good comment. When I made the comment I made, I was actually making it from the standpoint of what happens in the thinking of a large vendor which is not necessarily good for the industry, and so I think your comment makes sense, and I appreciate it. I know you're rushing to catch a plane, and I appreciate your participation. Other comments about what's written here on what first I would call the concern side?

The other two points that I made were that the FDA focuses on problems. This is 9B. Number 9 is because the rest of the document has 8 points before hand, but 9B, the FDA focuses on problems caused by individual devices, does not seem to cover situations or problems that occur even though the software's operating correctly. Anybody have any comments about that?

The next one was the FDA has a focus on serious injuries and death. When the FDA gets involved, it's usually some egregious situations, some terrible situation that occurred, and the comment here is that we need to make sure we have a reporting process that's sort of like a little bit further upstream that focuses on unsafe conditions … or an incompatible work process system. Again, not hearing any comments, so I assume that's okay.

Carl Dvorak – Epic Systems – EVP
Yes, and would agree with that and reinforce it. I think the kinds of problems that people spoke about during the meeting and the testimony, some of which we're certainly guilty of, just simply aren't addressed by what the FDA does, so if the mission is really to build a safer system, I don't know that the FDA actually significantly contributes towards that mission.

Paul Egerman – eScription – CEO
Right, and who just spoke?

Carl Dvorak – Epic Systems – EVP
Carl again, sorry.

Paul Egerman – eScription – CEO
Thank you, Carl. Is what's written here good enough? Do you want to expand it in some way or change it in some way?

Carl Dvorak – Epic Systems – EVP
I'm fine with what's written here.

Paul Egerman – eScription – CEO
Okay because this needs to be your document.

Joan Ash – Oregon Health & Science University – Professor and Vice Chair
This is Joan, and I'm thinking that for both and B and C you might want to mention something about the fact that a device is imbedded into a larger sociotechnical system, and the FDA process does not address the rest of the system.

Paul Egerman – eScription – CEO
A larger sociotechnical system, is that what you said?

Joan Ash – Oregon Health & Science University – Professor and Vice Chair
Well, that's just one term for it.

Paul Egerman – eScription – CEO
It's a great term. I have to confess, Joan, it's a term I would never use, but it's a wonderful term, so it's great. That's a terrific description. It's imbedded in a larger sociotechnical system because it does sort of capture something that I couldn't figure out how to say, in other words, that these systems are a little bit different than I think a lot of what FDA has been doing so far where you have a device and it's interacting with one person, a clinician or somebody's using it. This is part of sort of a larger process.

Joan Ash – Oregon Health & Science University – Professor and Vice Chair
Exactly.

Paul Egerman – eScription – CEO
How do I say that?

Joan Ash – Oregon Health & Science University – Professor and Vice Chair
I can send you something.

Paul Egerman – eScription – CEO
Yes, if you could send me something because I think that captures something really important that somehow I was trying to say. I don't think it came across, so I appreciate that. Other comments on this, on what I call the concern side?

Okay, so then not hearing any other comments, what I wanted to do was turn to what I call the collaboration side. We looked at the FDA, and first I have to tell you Jeff Shuren, Doug Wood, Parul Patel, the people at the FDA, they're good people who are trying hard. They answer their phone calls. They send emails. They ask questions. Paul Tang, I asked some questions about the QSR process, and they sent me some stuff even though some of it was already on their Web site. They showed me where I could get it. They were very responsive, and there are problems out there, too, in the real world, and there's a lot of knowledge within the FDA, so I said also let's look at the positive side.

How can the ONC work with the FDA in terms of recommendations we could make. The two recommendations that I wrote down here, one was to collaborate on certification criteria that improved patient safety, and some of this goes to the question you asked, Paul Tang, which is about quality systems. The picture I was hoping for here is that somehow ONC and the FDA could work together and look at their QSR process and say what are the parts of that that worked good for EHR systems and can impact patient safety. Let's do those parts and include that in certification and try to avoid the aspects

that seemed to be hampering innovation, or let's try to update the QSR process so it works right for EHR systems. There may be other things that they can help us with in certification. I don't know. What is people's reaction to the first comment there? Does that make sense?

Carl Dvorak – Epic Systems – EVP
How would you envision that? I guess certification is still a little bit murky, but any thoughts on how that would actually transpire?

Paul Egerman – eScription – CEO
Is this Carl asking a question?

Carl Dvorak – Epic Systems – EVP
Yes, it is. Sorry, I'll remember to say that next time.

Paul Egerman – eScription – CEO
Yes, this is Paul Egerman again. The way that would work is if you look at the NPRM it's very interesting. They made a distinction between certification and testing. Up until now in our industry, we viewed the certification process and testing as being synonymous and so testing is testing. Certification is other things.

Certification, for example, can include labeling requirements which the FDA does very well, but a labeling requirement sort of says how you have to represent your product, and that's what you have to do to get certified. Certification can impact other things, so certification can include having a quality development process. In can include, for example, that vendors have to record every patient safety complaint that they get from a customer, and vendors have to have some system of alerts to alert their customers of patient safety problems, and so that certification could include those capabilities. The FDA could help ONC in describing how to do an entire program about how you write that up and how you do surveillance to make sure it really is occurring. Vendors would have to somehow either present data or show that they have those processes in place as part of their certification process.

Carl Dvorak – Epic Systems – EVP
Basically, the way that that would work with a customer is because a customer would contract for certified systems and the certification would require that you have a process to report problems proactively to customers should you become aware of them, then it creates more or less an accountability liability wise directly from the customer to the vendor in the event that they don't record things that ultimately turn out to affect patient care? …

Paul Egerman – eScription – CEO
That's correct because—

Carl Dvorak – Epic Systems – EVP
… basically?

Paul Egerman – eScription – CEO
That's correct. In other words, the NPRM, the certification process does include surveillance to make sure the vendors are doing the right thing, so if a customer contracts with a vendor (We'll say it's with ABC Company.), then the customer makes his patient safety report and the customer notices that ABC Corporation doesn't send out an alert notice to all their customers because the customer would get the alerts, well then the customer can notify the certification organization and say this vendor isn't following the rules. The certification organization if they want can warn the vendor, can revoke their certification

which is actually fairly powerful because nobody wants their certification revoked because it damages them in the marketplace. There would be a process in place, although, as I said, the FDA probably could be very helpful in figuring out how to do that all right. The devil's always in the details of doing those things. Did what I say make, Carl?

Carl Dvorak – Epic Systems – EVP
Yes, it did.

Paul Egerman – eScription – CEO
What do you think? Is that a reasonable—?

Carl Dvorak – Epic Systems – EVP
I think so. I think that's a core responsibility that every vendor should have to try to prevent problems.

Paul Egerman – eScription – CEO
Other questions or comments about this first comment about collaborating on certification criteria to improve patient safety?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Paul, it's Larry. One of the things I thought was helpful in this recent discussion that we just ended was the reminder that certification is not just the technical testing of the software. I'm not quite sure how that would make its way into this recommendation, but I think that discussion was really good.

Paul Egerman – eScription – CEO
Maybe somewhere along the way I need to include a comment that reminds people that.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Yes.

Charles Kennedy – WellPoint – VP for Health IT
Paul, this is Charles. I guess a question I would have is I've been listening to this discussion. I came in a few minutes late. What is the FDA's stance on a quality assurance process which is designed to detect problems, resolve them especially as they come to patient care versus something that's more an adherence to a set of protocols for certification where there might be commercial consequences? In other words, how do they kind of separate out the need to foster open and honest discussion versus this software screwed up, and it needs to be taken off the market?

Paul Egerman – eScription – CEO
Charles, I'd say good morning and welcome. I don't know the answer to that question. I can't tell you that I know FDA and can tell you what their viewpoint is on that question. It's a good question.

Charles Kennedy – WellPoint – VP for Health IT
I guess my underlying point is when I go back to when I used to practice in the hospital we carved out certain areas so that these issues could be resolved, and it seems like in this discussion I'm not clear on what's carved out for the purpose of quality improvement and what, kind of, you screwed up. Your product's off the market because I think it's challenging if you don't separate them. If you try and mix those discussions, it I think tends to make both suboptimal.

Paul Egerman – eScription – CEO

Yes, that makes sense, although as I look at it, we have a certification program. We're required by the law to have one, and we should just do our best to make it as good as it can be. This is a way that we can put some patient safety concepts into it. It's sort of like something sort of independent of a lot of other of the issues that we have. Your comment about what happens when somebody screws up and you take it off the market, whether or not that's an important part of this discussion is a valid issue, but from the ONC standpoint, the public policy lever that we have with vendors is certification. It's actually a very powerful lever …. If a vendor loses their certification, that's significant in terms of their ability to market their product.

Charles Kennedy – WellPoint – VP for Health IT
Fair enough.

Paul Egerman – eScription – CEO
I don't know if I answered your question.

Charles Kennedy – WellPoint – VP for Health IT
Yes, I think what I'm hearing you say is this is more a commercial you lose your certification kind of thing and less on the quality assurance per se side of things which is fine.

Paul Egerman – eScription – CEO
Okay.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Paul?

Paul Egerman – eScription – CEO
Yes?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Yes, this is Paul Tang. I have a question, well, it's a comment. We just sort of fundamentally changed what an EHR certification body does and the requirements on that certification agency. It's beyond, okay, I'm going to accept this testing result for this software product to let's consider the processes in place to deal with as Joan said the sociotechnical and legal safety ramifications of using this software. That seems very different. It could call for different skills, different processes, and different kind of certifying body, so I just wanted to be aware of that because if we don't say the FDA is … organization for this particular topic, we've got to understand that we can't just pick a certifying body off the street and have them do the various things that we want them to do here.

Paul Egerman – eScription – CEO
Paul, this is Paul Egerman. That's a great comment, and I agree with that comment. I would make the observation that what is written here, though, I think is consistent with what's in the NPRM. The idea that you're going to make a distinction between a certification process and a testing process implies that certification includes something more than just testing which is what we've done so far.

It is correct, though, that we're going to be asking these certification organizations to do other things. We've already started to do that I think by suggesting that they also have to get involved with labeling issues which was one of our recommendations from the last call, but that's an important issue, too, because there's a lot of confusion about what it means to be certified. I think we will see the certification bodies do a broader range of activities.

You are correct that the existing certification organization, CCHIT, I do not know whether or not they can currently do this, but I don't think it's outside the realm of their skill base to be able to do something like this. It's a good observation. Does anybody else have any comments on what Paul Tang just raised?

Charles Kennedy – WellPoint – VP for Health IT
This is Charles, and Paul is kind of getting at the issue, probably saying it better than I was which is when you broaden out the notion of certification, you do get into some additional things. I'm wondering if what the NPRM and the notion of a certification body doing more than just testing, are we moving into the realm of more accreditation?

I don't know if this is helpful, but when we were setting up CCHIT, we tried to draw a line in the sand of certification was testing and ensuring the product performed against a set of standards and expectations. We consciously tried to stay away from accreditation which we thought began to involve the use of the product and how you use it and whether you get into patient safety issues. It sounds like with the NPRM we're moving kind of more into that latter category which, again, when we started CCHIT, we did try and consciously stay away from because it did broaden out the amount of things that you have to take on.

Joseph Heyman – AMA – Board Chairman
This is Joe. Can you hear me?

Paul Egerman – eScription – CEO
Yes, please go ahead, Joe.

Joseph Heyman – AMA – Board Chairman
Well, I think one of the points that Paul made that I think is really important is that it does sound a little bit like we're suddenly thinking of the FDA as one of the certification organizations, so I think we certainly need to make it clear that we're not discussing that as an issue.

Then the second thing I would say is being on the Joint Commission Board, one of the benefits of being an accreditation organization instead of the certification organization is the ability to ensure that a process is in place without dictating what the process has to be. In other words, we have lots of standards at the Joint Commission where we would say that a hospital, for example, has to have a process in place where there's a peer review, for example, of any sentinel event of something in that, but we don't dictate to them exactly how that process should be handled. We just want to make certain that they do have a process. I think with the certification organization it sounds to me from this distinction that with the certification organization you would actually be examining the process itself and deciding whether or not that process is good enough or something.

Paul Egerman – eScription – CEO
I'm trying to understand what you just said, Joe. Are you saying that to have certification do some of things, is that a good thing or not a good thing?

Joseph Heyman – AMA – Board Chairman
I'm not saying that it's a good thing or not a good thing. I guess what I'm trying to say is if you're concerned about innovation it seems to me that it's better to say something in the direction of you need to have a process in place that accomplishes X, and then when you certify the product or you're accredit it, either way (It doesn't matter to me which way you call it.), you look at that process and make sure it really does do what it says it's going to do. In other words, if you go in and inspect their organization or the product, you make sure their process does accomplish that, but you don't dictate to them what that process has to be. You only dictate to them that there has to be a process that accomplishes something.

Paul Egerman – eScription – CEO
That's a good description, Joe, because I what I was hoping we would be able to do because in some sense this discussion is a little bit of a discussion about another recommendation we already made that I thought we had agreed on, but what I was hoping that we'd be able to do would be to create a certification process exactly as you said, Joe, that would somehow make sure that vendors were giving patient safety alerts to their customers if they had reasonable internal processes in place, but perhaps with a little (I don't know if the right word is less.) proscriptive, less specific about what that process was. It would be an alternative to the class 2 regulation, to the QSR approach so that it would accomplish the goal in a different way.

Joseph Heyman – AMA – Board Chairman
Right, I got you. That's exactly what I'm trying to suggest. I'm trying to focus on the ability to innovate at the same time to be safe.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
This is Paul Tang. I just want to pick up on what Charles said. I think Charles hit the nail on the head. In other words, we have gone, this is not just …, but we are now incorporating things more than certifying that a product meets the spec. We are accrediting the process by which a vendor … as well as monitors and acts upon patient safety report. That's a process, and you accredit the organization. You don't certify the product. I think that's a really good point to capture the way Charles expressed it.

Paul Egerman – eScription – CEO
In capturing that what I'm trying to understand is are we capturing that as part of our recommendation, or is this a point that people are concerned enough about that they don't want to make this recommendation?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
I think you're calling the question. We sort of said, well, here are the concerns we have about the current FDA process which includes the QSR process, but it is … CCHIT process or their current skill set, … develop these new skills of accrediting an organizations process. Calling that question is a good one by saying we're concerned about the current FDA process. I think that means, or at least for me it doesn't mean there shouldn't be something more than certifying product.

Paul Egerman – eScription – CEO
I just want to—

Joseph Heyman – AMA – Board Chairman
Paul, this is Joe. Are you suggesting that we should limit certification to certifying organizations and suggest that if the process goes beyond certification and their examination of an organization processes rather than the product itself that some other entity should be doing that?

Paul Egerman – eScription – CEO
Which Paul are you asking the question of?

Joseph Heyman – AMA – Board Chairman
Paul Tang.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

No, I'm not suggesting that. The way Charles stated it at least makes clear the different activities of an organization. To contrast it with the existing certification process by CCHIT where they certify products, there's another kind of a function, and I think to label accreditation of processes that happen in an organization that has to occur, whether it's by certifying bodies that ONC (I don't know if the term is accredit.) endorses or it's a new organization. Hopefully, it's one in the same so there are not too many people there.

Charles Kennedy – WellPoint – VP for Health IT
Right.

Joan Ash – Oregon Health & Science University – Professor and Vice Chair
This is Joan. On the other document that we'll be discussing, we did even mention the Joint Commission. We said accreditation organizations like the Joint Commission can play an important role, and we go on a little bit, but maybe this discussion can help us amplify that when we get to it.

Paul Egerman – eScription – CEO
That makes sense.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
If the Joint Commission accredits healthcare organizations and the organization we're talking about right now is the vendors, right?

Paul Egerman – eScription – CEO
That's correct.

M
Although we do some accreditation of durable equipment stuff, we don't do a lot of it, but I know we have some standards about durable equipment.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
It doesn't matter who does it, but there's a different process than we have now. I guess that's to make a point.

Paul Egerman – eScription – CEO
I want to get back to Paul Tang's comment about calling the question. This question is this. On the one hand we could say we're changing the certification process to include not just testing, but also to include making sure that there are appropriate processes in place like patient safety alerts, and that's the reason to collaborate with the FDA to try to create that. The issue is should we just explain that and say that's part of our recommendation, or do we want to say no. We don't want to do that at all. We want to just limit it to testing. We don't like the QSR, but we're not going to come up with any alternative to it, either.

Joseph Heyman – AMA – Board Chairman
Paul?

Paul Egerman – eScription – CEO
Yes.

Joseph Heyman – AMA – Board Chairman
I think using patient safety alerts is not that great of an example because that really is part of the product rather than a process. I think when you're discussing a process, what you're talking about is there's a

process within the development of the product that ensures that the product itself doesn't malfunction in a way that would be harmful to patients.

Paul Egerman – eScription – CEO
This is an issue of quality processes?

Joseph Heyman – AMA – Board Chairman
Right, if the product is going to have a specific function, then it is certification, and then you're certifying that the product does the thing that it says it's going to do.

Paul Egerman – eScription – CEO
You're sort of suggesting that you're okay with the concept of certification including patient safety alerts, but it's the issue of the quality process itself that might—

Joseph Heyman – AMA – Board Chairman
Within the company because I thought that that's what the FDA was approaching. I thought the FDA was approaching making certain that the product itself is safe.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Well, let me see if this gets covered by what you're saying, Joe. One of the things I think we were saying is a vendor of EHR software must be able to receive, investigate, and act upon patient safety concerns that are submitted by its customers and in so doing, one, influence the way it designs and QAs products, but also, two, put out customer alerts about that product. Would that be covered under—

Joseph Heyman – AMA – Board Chairman
Exactly.

Paul Egerman – eScription – CEO
Then the second part is whether or not certification can include this sort of quality assurance process, a development process or other processes. Is that what you're saying, Joe?

Joseph Heyman – AMA – Board Chairman
Joe Heyman?

Paul Egerman – eScription – CEO
Yes.

Joseph Heyman – AMA – Board Chairman
I guess I'm saying I'm just sort of pointing out the difference that I see between certification and accreditation. I'm not sure I feel strongly one way or another about whether you have to have a separate entity or whether it can be the same entity or whether or not, I think we're all agreeing that somebody ought to do it, so whether it's the certification organization or a separate organization is not that material to me.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
One way to handle it, Paul, (This is Paul Tang.) is to make we describe what we expect to be done with respect to patient safety concerns, and then let the people who understand whether this is certification or accreditation handle that.

Paul Egerman – eScription – CEO

Well, yes. Accreditation in the NPRM is really used for a different function. It's really accrediting the certification organizations. In the terminology of the NPRM, it's really certification. The issue really becomes who's going to do these quality assurance processes. Is that a certification process, or is that an FDA process?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
I think it's a little bit more open that that. In other words, yes, the NPRM describes an entity that accredits certifying bodies, and the reason is because you're accrediting the makeup and processes by which the certifying body works. Similarly, we're saying there may be a counterpart in the vendor world or the healthcare organization world where that organization and its processes need to be accredited, much like the Joint Commission does. Do you see what I'm saying? The act of accrediting is the same, but they're two different purposes. We may want to just describe what it is that we think needs to occur above and beyond certifying functionality in a product in order to improve the safety of EHRs and their use.

Joseph Heyman – AMA – Board Chairman
Paul, this is Joe. I'm going to leave you guys. Sorry about this. Bye-bye.

Paul Egerman – eScription – CEO
We say what we want to occur, but the only entities that could do it right now are the FDA in certification unless we create a third entity which is going to be tough. Let's get back to the basic recommendation where we said we wanted to collaborate with the FDA on certification criteria to improve patient safety. Should we just delete it then? This is a discussion about FDA collaboration.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Well, the FDA has advice to give us about the process. That's all we meant by that, right?

Paul Egerman – eScription – CEO
That's correct.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
We don't want to not talk to them because I think also they're actively interested in the area, so we should collaborate with them.

Paul Egerman – eScription – CEO
Okay, that makes sense. I understand that, so I'll do my best to write this up. Are we ready to move on to the second recommendation, the second collaboration issue?

What I tried to do with the second collaboration issue is also point out that just in HIT and EHR systems there are some areas that are sort of like outside the reach of ONC that are creating problems. I gave the example which is meant to be an example of retail pharmacies that don't process electronic cancellation of orders, and as a result you can overmedicate a patient. What I wanted to do with that example is say, well, maybe this is an opportunity that FDA could collaborate with ONC to everybody's benefit. What do people think about this issue? Does this make sense, or is this not a reasonable recommendation or a comment? Does silence mean this is okay? Paul Tang, what do you think of this comment?

Charles Kennedy – WellPoint – VP for Health IT
Paul, this isn't Paul Tang. This is Charles. Maybe I'm not understanding the example correctly, but this is a retail pharmacy whose software does not process medication cancellations.

Paul Egerman – eScription – CEO

That's correct which is true like in 80% of them, and so the concept here would be that ONC would say as we look at the industry here are problem areas that we see and basically turn those over to the FDA and say can you help us in these problem areas. Is there something you can do to get these systems to do the right thing because it's a patient safety risk that they're not doing the right thing?

Charles Kennedy – WellPoint – VP for Health IT
These are the retail pharmacy systems that don't come under I guess any certification requirement that ONC is involved with at this point, right?

Paul Egerman – eScription – CEO
That's correct.

Charles Kennedy – WellPoint – VP for Health IT
Okay, now I've got you.

Paul Egerman – eScription – CEO
In other words, as far as I know, ONC doesn't have any public policy levers to help us with this, so they actually have two problems that I know of. One is they don't process cancellations which means, again, you can overmedicate patients. Although it means, I guess, they can sell more drugs, but you can overmedicate patients. The other thing they frequently don't do is give compliance data back to the ordering physician, and the physicians would like to get compliance data because if you're a cardiologist and you want to make sure your patients are taking their drugs, this is valuable information. Those are the two things. That would be the idea would be to address sort of hot topics and ask the FDA if they can help us with those.

Charles Kennedy – WellPoint – VP for Health IT
Got it. I don't know the FDA's capabilities in this space very well, but that's certainly a need. One of things, just to give you maybe another example, when I go out and visit retail pharmacies, a lot of them are taking the e-Script, dumping it to paper, and then rekeying it into their retail pharmacy system which kills a lot of the value of the e-Script. That's a little closer to home, but if the FDA or another entity could help us with that component, I think that's fundamental to getting value from these solutions. I think it would be a good idea. It's just I don't know their capabilities in this space.

Paul Egerman – eScription – CEO
Okay, any other comments? Are there any other ways that you think ONC and FDA could collaborate with each other?

Carl Dvorak – Epic Systems – EVP
Is there more opportunity for CMS to just interact directly? Again, I don't know that FDA really has the right set of skills or processes to enforce that sort of thing with the pharmacy. I wonder if that might be something put down as a CMS requirement who ultimately ends up paying for some portion of these jobs and make that a mandate.

Paul Egerman – eScription – CEO
I don't know if CMS can do that. I would think that the FDA has that in their umbrellas. They have the ability to regulate all of HIT software. It is an HIT system. It would seem to me, the FDA is an interesting organization. I mentioned once that there's some trepidation associated with the FDA, and just sometimes the fear that the FDA might do something can be enough to get an organization or an industry to change. I just view them as potentially a valuable ally.

A lot of examples, look at PAC systems. Most PAC systems don't connect to electronic medical records systems, so radiologists read stuff off their PAC systems and in a completely system have to barcode or manually enter the patient identification data. It's almost a variation of what Charles just said about how pharmacies work. Well, when you have dual systems like that that don't connect, there's a huge opportunity for problems. Those could be interesting things that the FDA might helps us with.

Carl Dvorak – Epic Systems – EVP
Okay.

Charles Kennedy – WellPoint – VP for Health IT
What would they actually do? What would we ask the FDA to do in such a circumstance?

Paul Egerman – eScription – CEO
Well, I think what they could do is, for example, the retail pharmacy area is regulate those software systems. They would say if you're using a software system it has to process electronic cancellations. It has to process electronic orders. It has to do these things, and the vendors have to do that, and you can't sell systems unless they do it. I'm certainly not an expert on it, but it seemed to me the FDA has a lot of capabilities to address these kinds of things.

Charles Kennedy – WellPoint – VP for Health IT
Okay, that makes all the sense in the world.

Paul Egerman – eScription – CEO
That would be the comment. The question is, is there anything that we should suggest in terms of collaboration?

Then let's briefly go to the recommendation. We looked at all the concerns in the collaboration in terms of recommendation. I don't know what people think about this, but the recommendation was simply that the ONC work with the FDA to determine the role the FDA should play to improve the safety of certified EHR technology, and then I said broad public participation which Joe Heyman wants to clarify which is excellent clarification, including the public, including patients, clinicians, and healthcare organizations should be involved in that discussion. This is not just a discussion we could do very briefly. We need to have a really thorough review of this entire topic. Are people comfortable with that?

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Yes.

Joan Ash – Oregon Health & Science University – Professor and Vice Chair
Yes.

Paul Egerman – eScription – CEO
Now, let's take a step back because the FDA discussion is certainly an emotional and important discussion. If we look at this document as a whole as to what we've said so far, are we comfortable that this is the right way for our workgroup to go with this? We're laying out some concerns. We're laying out some recommendations for collaboration, and we're basically asking for a thoughtful and careful analysis of the role. Are we comfortable with this? Is anybody not comfortable with it that maybe want to speak now or forever hold their peace? I want to make sure everybody has a chance to say something if you're okay with this approach.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Paul, it's Larry. I'm fine with this approach for what we're doing here, but we've touched on some topics today, talking about a broader understanding of certification heading towards accreditation perhaps, and we've talked about that sometimes the problem with systems is not the system narrowly defined in terms of the technology, but the larger technical and social context in which it's being used. The third piece is that EHRs are the narrow focus of our effort, but as we keep saying, health IT is broader than that, and there are often critical interactions with systems other than the EHR that are really needed to achieve the goals. I wonder if those need to find a home somewhere. I don't think they're actually in this safety recommendation. I think they're a broader set of comments. Maybe they go in the NPRM comments.

Paul Egerman – eScription – CEO
Those are excellent comments, Larry. There is a place we could put this. What you just said, Larry, is very helpful, but when I put out the documents for this discussion, I put out the FDA discussion, and I put out the rest of the recommendations, but there's actually a first half to that whole working document which was a discussion of what we learned and what our observations were before we get to the recommendations, and maybe that's where we could put this.

We could have a little transition between that first half and the recommendations where we would spell out, well, these are our observations that are very interesting which is that perhaps there needs to be a broader understanding of certification beyond testing, that these systems need to be looked at in a sociotechnical context, and that there's also critical interactions with HIT systems that are outside of certified EHR. We certainly saw that on the issue of laboratory interfaces where there are a lot of issues with connections between physicians and commercial labs that are also outside of ONC's regulatory process.

William Munier – Center for Quality Improvement and Patient Safety Agency – Director
This is Bill Munier. I'm going to have to go, but I just wanted to support what you're saying right now. Event reporting systems are outside as well, but need to get populated with EHRs and … angle that I'm obviously involved with. I apologize for having to leave early, but I'm comfortable with the directions you're going, and I have a prior to commitment that I'm going to have to go to.

Paul Egerman – eScription – CEO
Okay, that makes sense. Listen, Bill, I really appreciate your joining our workgroup and appreciate your participation.

William Munier – Center for Quality Improvement and Patient Safety Agency – Director
Yes, well, thanks much. Bye-bye.

Paul Egerman – eScription – CEO
Anyway, getting back to what you said, Larry, I think that's an excellent summary of major issues and sort of lumps them together, so my suggestion would be to put them into our document of learnings and observations that's going to precede all the recommendations.

Judy Sparrow – Office of the National Coordinator – Executive Director
Paul, this is Judy. Just so you know, in a formal recommendation letter, there is a section for your background or your introductory comments.

Paul Egerman – eScription – CEO
Terrific. I think that's all important. It's important stuff in terms of how we got to where we are. That's what we'll do. Are there other comments before I change the agenda and start going through the recommendations document? Any other comments about this whole FDA discussion?

Then moving onto the other document, that's the draft recommendations. What I tried to do here was write up our phone conversation from last week, and some of what I did was make some changes, and a lot of what I did was like rearranging the furniture. I sort of changed things around. If you have that document in front of you, it's called adoption and certification workgroup draft recommendations.

It starts out establish a patient-centered approach to HIT safety. What we did here was we made the goal shorter. Then when it came to the recommendation, before we had recommended like a national PSO, and what had happened as we discussed this in front of the policy committee and as I got the feedback from last week, we were talking back and forth as to what a PSO could and couldn't do.

The comment that was made (I think it was by Paul Tang.) was rather than talk about what a PSO does, let's talk about what it is we want to have happen, and so instead of recommending a PSO specifically, what we're recommending is sort of like a national information system and oversight system that could be like a PSO, but has the following capabilities. Then we listed out these capabilities like confidential reporting with liability protection and a capability to investigate serious incidents. We listed out these issues. I want to make sure that everybody understands that that's what we're doing. It's a little different than last time and also if you've gone through this list to make sure that these concepts of what I wrote down here on the list are correct, the confidential reporting, the ability to investigate serious injuries, standardized reporting, data formats, reports coming from patients, clinicians, vendors, and healthcare organizations. I won't read them out loud. Have people had a chance to look at this, and are you comfortable with this approach?

Joan Ash – Oregon Health & Science University – Professor and Vice Chair
This is Joan, and I've already sent you my comments.

Paul Egerman – eScription – CEO
Yes, and I'm looking at your comments right now, Joan. If I'm interpreting right, most of these are wording comments.

Joan Ash – Oregon Health & Science University – Professor and Vice Chair
Yes, nothing very substance …. You did such a good job.

Paul Egerman – eScription – CEO
Thanks, so these are wording comments. I don't see that you're substantially changing the content of what was written. You're just making it clear to the rest of the world what I really intended which I really appreciate.

Joan Ash – Oregon Health & Science University – Professor and Vice Chair
Except that I thought the information system as proposed might be misleading, and I don't know if the wording I put in, oversight mechanism, really does it either.

Paul Egerman – eScription – CEO
Why do you think information system is misleading, because it's more than an information system?

Joan Ash – Oregon Health & Science University – Professor and Vice Chair
Yes, information system to me means something much more technological.

Paul Egerman – eScription – CEO
I see.

Joan Ash – Oregon Health & Science University – Professor and Vice Chair
Is it truly an oversight mechanism because all of these things go beyond an information system I think, like the ability to investigate serious incidents, it's more of a mechanism or a process I guess is the word we've been using.

Paul Egerman – eScription – CEO
Well, is it a safety organization? Should we say national transparent safety organization? Is it a framework? Is it a structure? I'm not particularly good at the words. What's the best way to summarize it or to say it?

Joan Ash – Oregon Health & Science University – Professor and Vice Chair
Well, maybe oversight is a good word and mechanism or process or structure. It doesn't really matter.

Paul Egerman – eScription – CEO
Would you be okay with oversight process and information system?

Joan Ash – Oregon Health & Science University – Professor and Vice Chair
Of course.

Paul Egerman – eScription – CEO
Well, we'll try for that unless anybody else has comments. Then not hearing those any comments, then the other thing to make sure everybody understands that we added was that, I think we sort of strengthened the description of this formal study. We said that we recommend that ONC commission a formal study to thoroughly review HIT patient safety concerns and recommend additional action strategies to address those concerns, so not just a study to look at them, but it's actually to look at this very thoroughly and see what are the correct actions and strategies. I can't remember who it was, one of the presenters made a comment that it's sort a daunting process to think that we're going to create a national patient safety organization. That's a lot of work, and so we do need more research before we get completely comfortable with the right set of recommendations.

Then we have these seven or eight recommendations that came later, came after that. The first one's facilitate and encourage reporting. Again, this is me sort of like rearranging the furniture a little bit, but I sort of lumped together a number of things that we had before to facilitate and encourage reporting, so this is where I put in stage 2 of meaningful use certification criteria to make it easier for clinicians to immediately report problems and also complement regional extension centers providing training. I don't know if people thought it was okay to sort of lump it together, but that's what I was trying to do was to sort of explain a little bit more about why we were recommending to lump them all together.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Paul, it's Larry. A piece on the training part, I think we need to be looking at training bigger than just training on reporting.

Paul Egerman – eScription – CEO
Right, well, training also has a separate—

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
It does, but then again it seems like it's emphasizing reporting. It's sort of like teaching people to be proactively safe drivers. There are things you don't do.

Paul Egerman – eScription – CEO
Right, and it's a good comment, Larry. Actually, there was a series of emails before the call with Alan Morris and Ross Coppel. We were talking some of the limitations of training, but what I wrote here, certainly, it seems awfully brief, and you're right. It seems to be limited to reporting. What do you think we should be doing about it?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
I don't think there's any problem to encourage the reporting side. I guess maybe with eye towards brevity maybe if it just said including safety reporting training. Maybe the related piece here is HIT safety in the larger context of patient safety.

Paul Egerman – eScription – CEO
Explain what you mean there.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Let's take the whole med administration process. People have created manual processes about the checkpoints to make sure the right drug gets to the right patient, and we've added a lot of automation to further improve on that, everything from CPOE to …. You don't want a printout in the pharmacy to be rekeyed by the pharmacist. You want it to be electronic there, barcode med administration, so we've integrated a bunch of things, but there's still a training component about how you go about doing that and also how to look for the outliers that are going to tell you things aren't safe. It's analogous to it's getting cold and it's raining. Maybe I should pay attention to ice on the roads. It's increased safety with med administration. When things start to get really hectic, you've got to find a way to actually slow down, pay attention to the most important part of this.

Paul Egerman – eScription – CEO
It's interesting. I'm listening to you, and I'm thinking about Joan's earlier comment about sociotechnical systems. Is this a place where we should somehow draw that together?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Yes, maybe. Yes, that would work fine because with training we're teaching the people how to use this technology safely.

Paul Egerman – eScription – CEO
Right because the training needs to be not just how you interact with the computers. Somehow it needs to be how the entire process works. Is that what you're suggesting?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
—entire process works, or it's what to do when something looks odd to you. It's like I'm going to administer this med, but this is the first time I've seen this med on this patient. I don't ever remember seeing a new order. Is this really the right med for this patient? The barcode scanned okay, but this doesn't look right to me. I'm ad libbing here on the kind of sensitivity we're looking for people to have. To me that's the whole point of having human beings in the loop today and why we believe that humans add some safety factor. It's not that the robots haven't caught up yet, just don't have the dexterity to administer the med, but we actually have an opportunity for critical thinking at various points along ….

Joan Ash – Oregon Health & Science University – Professor and Vice Chair
This is Joan, and I really support what you're saying, and maybe we could partly get at it by instead of just saying patient safety reporting training, we could say something about the whole context of both education and training because I think of education as being much broader. I'm really an advocate for

consciousness-raising and helping the clinician learn to be diligent about entering accurate data into systems and just being aware all the time that whenever they're interacting with the system they need to be careful about it.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
I guess maybe to a point that Joe raised during the hearing was that in some ways we're looking for people to take their HIT training as seriously as they would take training in any medical procedure. We just don't throw people into an operating room and say good luck. We have a very complex and lengthy training process. As people develop new procedures, there are lots of continuing ed stuff around the new procedures and lots of in-service training around new procedures. We have a long history of a lot of training in how to do things in healthcare. I guess maybe this is an opportunity to kind of reinforce that message.

Paul Egerman – eScription – CEO
Is that Marc Probst talking?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Sorry, it's Larry again.

Paul Egerman – eScription – CEO
Larry, okay. Those are excellent comments. Those are really excellent comments. I'm trying to think about it. As much as I like those comments, I don't think that I can self-capture this correctly. Is there a way I can ask you, Larry and Joan, to draft some wording to help me fix this?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
I'll take a shot at it.

Paul Egerman – eScription – CEO
The concepts are great, and again, it relates a little bit to Joan's comment about sociotechnical environment, but I think it's terrific, so if you don't mind doing that, we need to keep it short. It should be like a paragraph, but let's go ahead and write that out.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
I'm going to have to apologize for, this whole bullet is about encouraging reporting, and you are correct to point me to bullet four which talks more about training in general.

Paul Egerman – eScription – CEO
What I did was I broke it in half. The first bullet was to encourage reporting. I think what's written there is correct. It's about encouraging reporting … for the regional extension centers, but when you started to make your comment, I sort of jumped us to topic number four because that's where I think your comment belongs, but topic four to listen to you and Joan is weak, and I think you guys can strengthen it quite a bit.

That's terrific, so let's move on to the second topic. This is where we get to the issues of vendor alerts. Basically, 2B has this business about the QSR program, and I'll try to alter that based on our discussion, so we'll probably take that out of the recommendation, but I'll put in something in its place.

Third one is patient engagement which I think we talked about before. I felt a little funny about putting patient engagement in as the third recommendation because I normally would want to do patients first, but just because we described the goal the way we did, I felt we needed to do all the sort of everything that dealt with communications in one shot, and then I did patient engagement. That's why, as I said, I

rearranged the furniture. I didn't change anything. It's just a little bit lower. I don't know if people are happy or unhappy with that.

Fourth was training that we just did.

Fifth was interoperability, and basically, what I tried to do here was capture the comments from last week which basically said for interoperability, this was an issue if you're still on the call that you had, Carl, but basically, we just say ONC's efforts are important, but we also capture, I forget who made the concept, the concept of traceability of interface transactions. Traceability refers to the ability to trace and analyze the source of problems. The one thing I added is a sense that we didn't discuss, but I tried to explain what traceability was. It was I said considered techniques like, I didn't say it had to be this technique, but like requiring the use of audit trails, so logs of interface transactions. I don't if, Carl, if you're still on the phone if that—

Carl Dvorak – Epic Systems – EVP
Yes.

Paul Egerman – eScription – CEO
Is that responsive to the—

Carl Dvorak – Epic Systems – EVP
I'm not sure that the traceability issue way my issue, Paul. I think that may have been someone else's. I think I raised the question of the notion of interoperability different from health system to health system versus interoperability within a health system to, like, modular software or something. I think that was more my issue. I don't know if traceability was someone else's.

Paul Egerman – eScription – CEO
I think it was George who's not on the call who raised it. Let me ask you, Carl, are you comfortable with what's written here?

Carl Dvorak – Epic Systems – EVP
Yes, I think because it is a little bit generic I think it's fine.

Paul Egerman – eScription – CEO
Okay, and what's your view of this traceability issue?

Carl Dvorak – Epic Systems – EVP
Fine. I think it is important to be able to reconstruct. I do think interpretation of it will be the trick. You could interpret it to such an extent that you'd have to triple your storage, but I think it's fine the way it is. I think the devil will be in the details as to how someone interprets it into actual rules and regulations.

Paul Egerman – eScription – CEO
That's right.

Carl Dvorak – Epic Systems – EVP
Conceptually, it's a very reasonable thing. You'd want to understand how did something get to be how it is so that you can get to a real cause and prevent it from reoccurring.

Paul Egerman – eScription – CEO

We have six which was the best practices. That's just, again, as I said, rearranging the furniture. Seven was accreditation which also I think was in, this was Joan's issue, but I didn't change the wording of this at all.

The number eight recommendation, this was the issue that Carl raised, and this was how I phrased it. This is this issue last week that Carl and Paul Tang talked about back and forth between the timing of stage 2 and stage 3, and Carl, what you had really wanted was some specific dates. I think Paul Tang was saying it's unrealistic, so what we came up with was, I came up with just a very general statement that we want stage 2 released as soon as possible and the recommendation that a late release of stage 2 is really going to make it difficult. It's really going to tie the hands of the meaningful use people to require significant new functionality for stage 3.

Carl Dvorak – Epic Systems – EVP
It really is the distance between the release of stage 2 requirements for certification and the stage 2 eligibility period. That's the real concern because that's what will create the rush to try to program it, get it out to sites, and have sites try to adopt it quickly. The certification requirements for stage 2 and the actual eligibility period of stage 2 are being too close together. It's less about the distance of stage 2 to stage 3, although that also crunches just simply because of the five-year time window, but the concern is the distance between the publication of stage 2 certification criteria and the beginning of the final eligibility, stage 2 eligibility period.

Paul Egerman – eScription – CEO
You want that tier to be as long as possible?

Carl Dvorak – Epic Systems – EVP
I think that an 18-month timeframe is a very reasonable timeframe. I think as it crunches down to nine months from knowing what to program to when it has to be in the hands of doctors and nurses using it I think is too short. As long as possible, maybe not necessarily that, but a safe and prudent window I think is about that 18-month timeframe.

Paul Egerman – eScription – CEO
Maybe I misunderstood it wrong because I had thought you were talking about the time period between stage 2 and stage 3. It's really the timeframe between when the certification criteria are published and when the eligibility period begins for both stage 2 and stage 3.

Carl Dvorak – Epic Systems – EVP
Exactly.

Paul Egerman – eScription – CEO
You're requesting 18 months versus, you'd like as long as possible, but 9 months is too short?

Carl Dvorak – Epic Systems – EVP
Yes, I think to request as long as possible is vague and probably longer than it needs to be, but either that or recognition that what gets written into the meaningful use requirements factor in consensus input from people who actually have to program it, vendors, open source providers, and home-developed systems to make sure that we don't put requirements in that can't be safely programmed in too short a window. Either make the window practical or have another constraint on the MU requirements such that you take feedback that this isn't safe to program and release to customers and adopt into production in a nine-month window. Either side of that equation if they both were enforceable or had some assurance that they would actually take place would be fine.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
This is Larry. Let me comment briefly. My sense is that even under the best of circumstances, nine months is a really tight timeline. There's a lot of training to do, and a healthcare organization of any size really needs to go through its own waves of training, and nine months can be a big crunch, so I like your notion of 18 months, both of you. That gives time for the developers to create something, to get it reviewed, get some feedback, modify it, get it back out, get it into the customer's hands, and then give providers a chance to implement. I like your suggestion that 18 months was in fact a good floor for the time.

Paul Egerman – eScription – CEO
Is 18 months the floor, or is 18 the preferred time? Let's talk about it specifically. Let's look at stage 2. When does this stage 2 eligibility period start?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Two years from October.

Paul Egerman – eScription – CEO
So that's October 2012.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Right.

Paul Egerman – eScription – CEO
So 18 months earlier would be what?

Carl Dvorak – Epic Systems – EVP
December of 2010.

Paul Egerman – eScription – CEO
We just set … last week that that's just impractical. They're not going to get it done by then?

Carl Dvorak – Epic Systems – EVP
I think that was the discussion last week. I'm not sure where to go with it other than the other side of the teeter-totter is really constrain what goes into the meaningful use requirements by accepting feedback on the practicality of implementing it safely, putting it through the appropriate cycles, and getting it safely into customer's hands. I think you'd have to accelerate completing them, or you have to now impose some practical feedback loop on limitations as to what can safely be done in that timeframe and push it out.

The question of how long is long enough is a direct function of how much are people asking to put in? What's the net new, and if the net new is significant, certainly nine months is not enough. Eighteen months might not be enough depending on how much is asked for. The part that's unknown is what's going to be asked for in stage 2. I don't know if there's any preliminary information out there and how certain that is, but it seems like we have to do one of the two things. Either get a long enough window to reasonably get—

Paul Egerman – eScription – CEO
Yes, the approach right.

Carl Dvorak – Epic Systems – EVP

What if we have to mobilize and blitz it? The other side of that coin is to provide some additional mechanism that limits what goes into the meaningful use requirements, what goes into the certification requirements.

Paul Egerman – eScription – CEO
Let me go back to, you said 18 months, but the eligibility period for stage 2 starts October 1, 2012, so 18 months, would that be April 1, 2011?

Carl Dvorak – Epic Systems – EVP
I think we anticipated it getting out to customers so they could get it into production a few months ahead and get the meaningful use because what happens is they have to not only get the software in place, they also have to change workflow process procedure data collection to support the meaningful use requirements, and I think that has to be done, although I'm not sure anymore, I think that has to be done for the entire eligibility period, doesn't it, for the 2012 one, or for stage 2 rather?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
That eligibility piece as my understanding as well that switches from three months to a year.

Carl Dvorak – Epic Systems – EVP
… I think my math is wrong. I don't think 18 months is December. I think it's later than that, but the December recommendation came from me, and that was originally because we wanted to leave a window of time for people to adapt their workflow and process to be able to be ready for meaningful use requirements that came with stage 2.

Paul Egerman – eScription – CEO
I agree that it's a daunting proposition because let's say you find out April 1 what your criteria are. Well, you've got to somehow program your systems and get certified against it. If you're lucky, you can get that done in maybe six months, but then you've got to get everything out to your customers, and they've got to somehow be able to test it before they use it.

Carl Dvorak – Epic Systems – EVP
That's assuming no wait for certification which when you look at what happens is you're going to get all the vendors lining up to start about the same time which means they'll likely try to certify at about the same time in order to get it to customers at about the same time. You'll see a tidal wave of certifications coming through all within probably a two to three-month period if most vendors approach it the same way.

Paul Egerman – eScription – CEO
Another way to approach this is it might be helpful to describe this. It's helpful what you just said that you're looking for 18 months between when the certification criteria are known until the time the eligibility period begins, but it might be helpful if we could put in an intermediate date also which says we'd like customers who've already qualified for stage 1 to be able to have the stage 2 software available to them X number of months before the eligibility period begins, so I don't know what that is, if that's a year, if that's nine months or six months. Do you understand what I'm saying to help people understand that there's another deadline in there?

Carl Dvorak – Epic Systems – EVP
I think every vendor probably has a slightly different experience, but my experience with larger sites is in order to put an upgrade in, it's typically somewhere in the three to six month of preparation, usually around four. If you really set your mind to it and work your way through it quickly, you can go from the delivery of a CD-ROM to a live in production of about four months. The smaller you are, the faster you

can go because you tend to have less interfaces, less workflows to validate, less specialties, fewer moving parts as a larger health system might have. Smaller places can get it down at the speediest probably a month, but even that's starting to be really quick.

When you just think about everything you have to do to digest all the new things that might come in … release. I would say it does vary by vendor and by organization size because sometimes a straightforward ambulatory clinic-only release is going to be simpler than a large multi-hospital ambulatory multi-specialty organization's release. I would say customers should have it somewhere three to six months ahead of having to have it in production. Again, if meaningful use requires significant effort to chance process, workflow, or procedure, you might even hedge that to the high side to give them time to get the software pieces in place and adjust and train their users for new workflow, new data capture.

Paul Egerman – eScription – CEO
Here's what I'm putting in my notes, Carl, and tell me if I'm getting this right. We'd like the certification criteria to be known, to be settled 18 months before the eligibility period so that people who qualified under stage 1 could have the software in place nine months before the eligibility period begins, so there are sort of two nine-month periods. There's nine months between the time the criteria is known until you're actually able to distribute to your customers, and then nine months from then to get it to test it, train their people, and be comfortable with it and put it into operation in order to make the beginning date on stage 2. Is that a fair—

Carl Dvorak – Epic Systems – EVP
I'd go maybe 12 and 6. I think, again, depending on what what's being asked for the nine on the development side might be too short. I think I'd go 12 and 6.

Paul Egerman – eScription – CEO
Okay, 12 being, the 6 being how much time the customer needs to have it.

Carl Dvorak – Epic Systems – EVP
To adapt to it, yes. I think it'll be cakewalk for smaller practices, and it'll probably be working hard for larger health systems.

Paul Egerman – eScription – CEO
I will try my best to rewrite this, and let me know if I get it right.

Carl Dvorak – Epic Systems – EVP
Thanks, Paul.

Paul Egerman – eScription – CEO
Then following through the documents, we get to the end. We have the FDA requirements that we just had, and any other comments about what we're recommending here? Are people feeling okay about this?

Carl Dvorak – Epic Systems – EVP
I think so, Paul. You must be good with silence.

Paul Egerman – eScription – CEO
Pardon me?

Carl Dvorak – Epic Systems – EVP

You must be getting good with silence.

Paul Egerman – eScription – CEO
With silence?

Carl Dvorak – Epic Systems – EVP
Yes.

Paul Egerman – eScription – CEO
Well, it's actually an interesting thing. With a wife and two kids, I'm usually the one who's silent. It's hard for me to know. What I'm going to do is I will write this up again, and then I will send out another copy, and I will leave it up to the workgroup members. What I'd be asking you to do will be to edit the copy, and edit means wordsmith it wherever you think something's wrong or tell me if you think something is incorrect in terms of what you think we talked about. I'm happy to go through two or three more iterations, but it's all aiming towards an April 21 presentation. If we go through this all and anybody thinks that they want to have another meeting between now and April 21 because we didn't cover something correctly or there's some confusion about something, I'm happy to do that.

I had one other question on the recommendations, one other idea I wanted to raise which is I came to it based on a comment that Joan made when we were talking about FDA, and she was talking about things being counterproductive. We were talking about the QSR system, she said, by itself could be counterproductive to patient safety if it harms development. A crazy idea I had which was to throw in a final recommendation which is to say something like the thing that could harm patient safety most of all would be a failure to implement these systems. What do people think about that?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
This is Paul Tang. I joined again. I was off for a half hour. That sounds like a nice concluding statement.

Paul Egerman – eScription – CEO
Yes, because the thing that I found really interesting was in the public comment period for the last policy committee meeting, I wish I could remember the name of the woman who said it. She got on the phone, and she actually gave a very passionate discussion. She said the Institute of Medicine study was done 1999, and 98,000 people are dying every year because we don't have these systems in place, and we've been talking about this thing, and we're talking about this thing, and people are still dying because we don't have these systems in place. Now the government's given us the money, and let's get on with it. I heard that, and I said, "Wow."

That was like a wakeup call to remembering why it is we're doing this thing. These things are intended to be things that improve patient safety. You're telling me you agree with that, that that's okay to end with that as a comment that the most important patient safety thing we can do would be to implement these systems.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
In a correct and appropriate and safe way. I think we just had a whole lot of these concerns, and we don't want to leave this discussion saying, well, maybe we better wait because I don't think that's the point, yet I think our point is that without additional precautions, we could be in a predicament, and also, it's not to say that we aren't having issues now that we would like to improve upon.

Paul Egerman – eScription – CEO

That's great. As I said, I'll do my best to draft something, especially on that statements, but on all the statements people should feel free to wordsmith it, and we'll go through a few iterations with the emails to try to write it correctly because I certainly agree with what you said. The issue is we don't want to just throw it out there. We want to do it correctly. The important part is this is the solution. This is the cure, and we need to keep moving forward. Any other comments? Everybody feels they've said what they want to say on these topics before I throw things open to the public comment period? Not hearing any other comments. Judy, why don't we open the lines to see if there's anybody in the public who'd like to make any comments?

Judy Sparrow – Office of the National Coordinator – Executive Director
Sure, operator, can you check and see if there are any public comments? While we're waiting, I guess, Paul Tang, I should mention to the group that the meaningful use workgroup is having a hearing the day before the HIT policy committee meeting on patient engagement. It will be on April 20, also at the Omni Shoreham.

Operator
We do not have any comments from the public.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. Paul Egerman, back to you.

Paul Egerman – eScription – CEO
Thank you very much. Let me thank the workgroup members. Let me thank the members of the public who may have listened over the telephone line and thank Judy Sparrow and the HHS people for their help. I wish everybody happy holidays in the holiday season, and thank you very much.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Paul. Bye.

Carl Dvorak – Epic Systems – EVP
Thank you. Bye-bye.

Public Comments Received During the Meeting

1. Do you feel that vendors will be able to handle the workload of all the customer implementations without causing further delays? Six months is a little optimistic to think that a vendor will be able to upgrade all their HIT systems to make them compliant with meaningful use. Many vendors are already putting customers on 10-month implementation waiting lists.

2. I represent a mental health service provider organization that develops its own EHR systems internally. I want to highly recommend against allowing the FDA to jump in with own certification requirements at this time, because it would create an additional serious barrier to innovation. From our perspective, CCHIT certification requirements are already expensive and onerous enough. We cannot afford another level of regulation that we are required to meet. Having the flexibility to develop our own systems has been a huge benefit to us. If the FDA does adopt an EHR oversight role, it must include adequate provisions to allow the freedom for self-developed EHR systems.